

January 31, 2002

SUBJECT: **Imazalil**. Reregistration List B Chemical Number 111901; Case No. 2325  
Revised Product and Residue Chemistry Chapters for the HED Risk Assessment.  
No MRID No. DP Barcode D272790.

FROM: Thurston Morton, Chemist  
Reregistration Branch 4  
Health Effects Division (7509C)

and

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Reregistration Branch 4  
Health Effects Division (7509C)

THRU: Susan V. Hummel, Branch Senior Scientist  
Reregistration Branch 4  
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TO: Dayton Eckerson  
Special Review Branch  
Special Review & Reregistration Division (7508C)

Attached is the revised Residue Chemistry Chapter for the reregistration eligibility document (RED). This revision serves to incorporate comments from the registrants which were deemed applicable to this chapter. This was originally completed by Dynamac Corporation under supervision of HED. It has undergone secondary review in the branch and has been revised to reflect current Agency policies.

Outstanding data required at the present time include:

GLN 830.7050, UV/Visible Absorption,

GLN 860.1340, analytical method for imazalil in livestock tissue and ,

GLN 860.1360, multiresidue method data for imazalil metabolites,

GLN 860.1480, residue data resulting from a fumigation application to poultry houses.

cc : Chem F, Chron F, Morton, Hrdy

RDI: SVH:1/31/02

TM, Thurston Morton, Rm. 816D CM2, 305-6691, mail code 7509C

# IMAZALIL

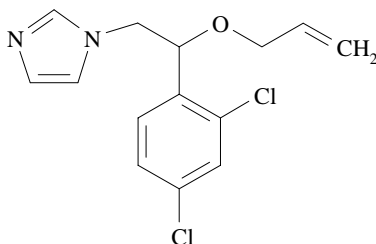
## REREGISTRATION ELIGIBILITY DECISION:

### PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 111901; Case No. 2325

#### DESCRIPTION OF CHEMICAL

Imazalil [1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1*H*-imidazole] is a systemic fungicide used for postharvest treatment of citrus fruits and bananas (foreign use) and for seed treatment of barley and wheat prior to planting.



Empirical Formula:	C <sub>14</sub> H <sub>14</sub> Cl <sub>2</sub> N <sub>2</sub> O
Molecular Weight:	297.17
CAS Registry No.:	73790-28-0
PC Code:	111901

#### IDENTIFICATION OF ACTIVE INGREDIENT

Imazalil is a yellow or brown crystalline solid with a melting point of 50 C, density of 1.348 x 10<sup>3</sup> kg/m<sup>3</sup>, octanol/water partition coefficient (log P<sub>ow</sub>) of 3.82, and vapor pressure of 3.6 x 10<sup>-4</sup> Pa at 25 C. Imazalil is slightly soluble in water (293 ppm at 20 C), and is very soluble in methanol, ethanol, 2-propanol, dimethylbenzene, acetonitrile, N, N-dimethylformamide, tetrahydrofuran, 1-methyl-2-pyrrolidinone, 1,2-ethanediol, 1,2-propanediol, and glacial acetic acid (>500 g/L at 25 C).

#### MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 1/22/02 identified two imazalil manufacturing-use products (MP) registered under PC Code 111901: the Janssen Pharmaceutic 97.5% technical (T; EPA Reg. No. 43813-2) and the Makhteshim-Agan of North America Inc. (MANA) 98.5% technical (T; EPA Reg. No. 11678-55). Both technicals are subject to a reregistration eligibility decision.

## REGULATORY BACKGROUND

The Imazalil Phase 4 Review dated 10/19/90 by S. Funk determined that additional data were required concerning all product chemistry guidelines except OPPTS 830.1550 (product identity) for imazalil; the product chemistry data submission for OPPTS 830.1550 was determined to be acceptable for Phase 5 review. Subsequent to the Phase 4 Review, all new product chemistry data have been submitted in support of the reregistration of imazalil.

The current status of the product chemistry data requirements for the imazalil T/TGAI is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

## CONCLUSIONS

All pertinent product chemistry data requirements have been satisfied for the Janssen 97.5% T/TGAI, except that additional data are required concerning UV/visible absorption (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table for the imazalil T/TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of imazalil with respect to product chemistry data requirements.

All pertinent product chemistry data requirements have been satisfied for the Makhteshim-Agan of North America Inc. (MANA) 98.5% technical T/TGAI, except that additional data are required concerning UV/visible absorption (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table for the imazalil T/TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of imazalil with respect to product chemistry data requirements.

## AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): 6098  
Subject: Dioxin Review for Imazalil  
From: S. Funk  
To:  
Dated: 2/23/90  
MRID(s): 40478201

CBRS No(s): 7014  
Subject: Product Chemistry Data Review for Technical Imazalil to Determine the Potential for Halogenated Dibenzo-p-Dioxin/Dibenzofuran Formation. Additional Data. I.D. No. 43813-1. Rereg Case No. 2325.  
From: S. Funk  
To: K. Davis  
Dated: 11/16/90  
MRID(s): 41595901

CBRS No(s): 7117  
DP Barcode(s): D156801  
Subject: Supplement to Phase 3 Registrant Response and Reply to Manufacturing DCI to Evaluate the Potential for Halogenated Dibenzo-p-dioxin/Dibenzofuran Formation. Reregistration Case No. 2325  
From: S. Funk  
To: K. Davis  
Dated: 5/10/91  
MRID(s): 41545101

CBRS No(s): 10342  
DP Barcode(s): D181284  
Subject: Imazalil. Product Chemistry Data and Stability of <sup>3</sup>H-Imazalil.  
From: L. Cheng  
To: K. Davis  
Dated: 9/25/92  
MRID(s): 40478201

CBRS No(s): 8845  
DP Barcode(s): D170516  
Subject: Reregistration of Imazalil. Janssen Pharmaceutica 97.5% T (EPA Reg. No. 43813-2).  
From: P. Deschamp  
To: J. Ellenberger/B. Briscoe  
Dated: 10/8/92  
MRID(s): 41606106 and 41889801

CBRS No(s): 11365  
DP Barcode(s): D187938  
Subject: Reregistration of Imazalil. Janssen Pharmaceutica Product Chemistry Data for their 97.5% T (EPA Reg. No. 43813-2). List B Case No. 2325. Chemical No. 111901.  
From: P. Deschamp  
To: K. Depukat  
Dated: 3/18/93  
MRID(s): None

CBRS No(s): 12010  
DP Barcode(s): D192069  
Subject: Reregistration of Imazalil. Janssen Pharmaceutical Product Chemistry Data for the 97.5% Technical (EPA Reg. No. 43813-2). List B Case No. 2325.  
From: S. Funk  
To: K. Davis/K. Depukat  
Dated: 8/12/93  
MRID(s): 42793800-42793802, and 42403101

CBRS No(s): 12920  
DP Barcode(s): D197279  
Subject: Imazalil. Case No. 2325. Janssen Pharmaceutical Product Chemistry Data §61-1 for the 97.5% Technical (EPA Reg. No. 43813-2).  
From: L. Cheng  
To: K. Depukat  
Dated: 3/8/94  
MRID(s): 43016801

CBRS No(s): 13708  
DP Barcode(s): D203270  
Subject: Imazalil Reregistration. Janssen's 5/5/94 Response [61-2(b) Data for Product 43813-2] to Agency 4/6/94 Letter.  
From: K. Dockter  
To: K. Davis/K. Depukat  
Dated: 7/18/95  
MRID(s): 43223001

DP Barcode(s): D231609  
Subject: Product Chemistry Review of Imazalil Technical.  
From: A. Smith  
To: J. Stone  
Dated: 4/10/97  
MRID(s): 44107201-11, 44107218, 44134401, 44134402, 44145401

## PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

### References (cited):

40478201 Goodwine, W. (1987) Product Identity and Composition [Imazalil]: IMZ-PC-61. Unpublished study prepared by Janssen Pharmaceutica. 334 p.

41545101 Goodwine, W. (1987) Product Identity and Composition: Imazalil: Lab Project Number: IMZ-PC-61. Unpublished study prepared by Janssen Pharmaceutica. 8 p.

41595901 Janssen Pharmaceutica (1990) 1, 3-Dichlorobenzene Manufacturing Process and Impurities: Supplement: Lab Project Number: IMZ-PC-61. Unpublished study. 8 p.

41606106 Crauwils, R.; Dingenen, J. (1990) Physical and Chemical Characteristics of Imazalil (R23979): Fungaflor Technical: Lab Project Number: IMZ-PC-63 (1). Unpublished study prepared by Janssen Pharmaceutica. 101 p.

41889801 Niusmans, S.; Lauwers, W.; Smet, M. (1991) Analysis and Certification of Product Ingredients Fungaflor Technical: Lab Project Number: IMZ PC-62. Unpublished study prepared by Janssen Research Foundation. 75 p.

42403101 Goodwine, W. (1987) Supplement to MRID 40478201: Product Identity and Composition, Guideline Series 61: Description of Beginning Materials and Manufacturing Process. Unpublished study prepared by Janssen Pharmaceutica. 7 p.

42793801 Nijsmans, G.; Lauwers, W.; DeSmet, M. (1993) Analysis and Certification of Product Ingredients Fungaflor Technical: Lab Project Number: IMZ PC-62: ST-BO GC-930323: ST-QA 93-8. Unpublished study prepared by Janssen Pharmaceutica. 72 p.

42793802 Crauwels, R.; Van Dingenen, J. (1993) Physical and Chemical Characteristics of Imazalil Fungaflor Technical: Lab Project Number: IMZ PC-63: 930409: PC-CHAR 93-17. Unpublished study prepared by Janssen Pharmaceutica. 21 p.

43016801 Janssen (1993) Supplement to Primary MRID 40478201 and Secondary MRID 41889801: Product Identity and Composition-Imazalil: Lab Project Number: IMZ-PC-61. Unpublished study. 13 p.

43016801 Janssen (1993) Supplement to Primary MRID 40478201 and Secondary MRID 41889801: Product Identity and Composition-Imazalil: Lab Project Number: IMZ-PC-61. Unpublished study. 13 p.

43223001 Goodwine, W. (1994) Product Identity & Composition: Discussion of Impurities: Imazalil: Supplement: Lab Project Number: IMZ-PC-61. Unpublished study prepared by Janssen Pharmaceutica. 7 p.

44107201 Morrissey, M. (1995) Determination of Identity, Purity, and Stability for Standards Used for Impurity Analysis of Magnate (Technical): Study Number: HWI6413-115. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107202 Registration Department, Makhteshim Chemical Works, LTD. (1996) Magnate (Imazalil Technical) Product Chemistry Data: Study Number: R9236. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107203 Morrissey, M. (1995) Analysis of Magnate (Imazalil) Technical and its Impurities: Study Number: HWI6413-116. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107204 Morrissey, M. (1996) Color Determination of Imazalil TGAI: Study Number: HWI6413-118. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107205 Morrissey, M. (1996) Physical State Determination of Imazalil TGAI: Study Number: HWI6413-119. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107206 Morrissey, M. (1996) Odor Determination of Imazalil TGAI: Study Number: HWI6413-120. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107207 Morrissey, M. (1995) Series 63 Product Chemistry Determinations of Magnate (Imazalil) Technical (Melting Point): Study Number: HWI6413-117A. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107208 Morrissey, M. (1995) Series 63 Product Chemistry Determinations of Magnate (Imazalil) Technical (Relative Density): Study Number: HWI6413-117B. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107209 Morrissey, M. (1995) Series 63 Product Chemistry Determinations of Magnate (Imazalil) Technical (Solubility in Organic Solvents): Study Number: HWI6413-117C. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107210 Teeter, D. (1996) Dissociation Constant Determinations of Imazalil TGAI: Study Number: HWI6413-123. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107211 Morrissey, M. (1996) Octanol/Water Partition Coefficient Determination of Imazalil TGAI: Study Number: HWI6413-121. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44107218 Hogg, A. (1991) Imazalil (Batch No: 1471-24/2) Determination of Vapor Pressure: Study Number: 306/59. Unpublished study Submitted by Makhteshim Chemical Works, Ltd.

44134401 August, J. (1996) pH Determination of Magnate (Imazalil) Technical: Study Number: CHW 6413-142. Unpublished study Submitted by Makhteshim Agan of North America, Inc.

44134402 August, J. (1996) Stability Determination of Magnate (Imazalil) Technical: Study Number: CHW 6413-142. Unpublished study Submitted by Makhteshim Agan of North America, Inc.



Case No. 2325  
Chemical No. 111901

Case Name: Imazalil  
Registrant: Janssen Pharmaceuticals  
Product(s): 97.5% T (EPA Reg. No. 43813-2)

### PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? <sup>1</sup>	MRID Number <sup>2</sup>
830.1550	Product identity and composition	Y	<b>40478201</b> , 42793800 <sup>3</sup> , 42793802 <sup>3</sup> , 43016801 <sup>4</sup>
830.1600	Description of materials used to produce the product	Y	<b>40478201</b> , 41595901 <sup>5</sup> , 41545101 <sup>6</sup> , 42403101 <sup>3</sup>
830.1620	Description of production process	Y	<b>40478201</b> , 41595901 <sup>5</sup> , 41545101 <sup>6</sup> , 42403101 <sup>3</sup>
830.1670	Discussion of formation of impurities	Y	<b>40478201</b> , 43223001 <sup>7</sup>
830.1700	Preliminary analysis	Y	<u>41889801</u>
830.1750	Certified limits	Y	<u>41889801</u> , Letter 2/9/93 <sup>8</sup> , 42793800 <sup>3</sup>
830.1800	Enforcement analytical method	Y	<u>41889801</u> , Letter 2/9/93 <sup>8</sup> , 42793801 <sup>3</sup>
830.6302	Color	Y	<u>41606106</u>
830.6303	Physical state	Y	<u>41606106</u>
830.6304	Odor	Y	<u>41606106</u>
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	<u>41606106</u> , Letter 2/9/93 <sup>8</sup> , 42793802 <sup>3</sup>
830.7000	pH	Y	<u>41606106</u>
830.7050	UV/Visible absorption	N <sup>9</sup>	
830.7200	Melting point/melting range	Y	<u>41606106</u>
830.7220	Boiling point/boiling range	N/A <sup>10</sup>	
830.7300	Density/relative density/bulk density	Y	<u>41606106</u>
830.7370	Dissociation constants in water	Y	<u>41606106</u>
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	<u>41606106</u>
830.7840	Water solubility: column elution method; shake flask method	Y	<u>41606106</u> , Letter 2/9/93 <sup>8</sup> , 42793802 <sup>3</sup>
830.7950	Vapor pressure	Y	<u>41606106</u>

<sup>1</sup> Y = Yes; N = No; N/A = Not Applicable.

<sup>2</sup> The **bolded** reference was evaluated in the Imazalil Phase 4 Review, 10/19/90, S. Funk and was subsequently reviewed under CBRS No. 6098, 2/23/90, S. Funk, and CBRS No. 10342, D181384, 9/25/92 L. Cheng (for OPPTS 830.1600 and 1620 only); underlined references were reviewed under CBRS No. 8845, D170516, 10/8/92, P. Deschamp; and all other references were reviewed as noted.

<sup>3</sup> CBRS No. 12010, D192069, 8/12/93, S. Funk.

<sup>4</sup> CBRS No. 12920, D197279, 3/8/94, L. Cheng.

<sup>5</sup> CBRS No. 7014, 11/16/90, S. Funk.

<sup>6</sup> CBRS No. 7117, D156801, 5/10/91, S. Funk.

<sup>7</sup> CBRS No. 13708, D203270, 7/18/95, K. Dockter.

<sup>8</sup> CBRS No. 11365, D187938, 3/18/93, P. Deschamp.

<sup>9</sup> The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

<sup>10</sup> Data are not required because the TGAI is a solid at room temperature.

Case No. 2325  
Chemical No. 111901

Case Name: Imazalil  
Registrant: Makhteshim-Agan of North America Inc. (MANA)  
Product(s): 98.5% T (EPA Reg. No. 11678-55)

### PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? <sup>1</sup>	MRID Number
830.1550	Product identity and composition	Y	4410702 <sup>2</sup>
830.1600	Description of materials used to produce the product	Y	4410702 <sup>2</sup>
830.1620	Description of production process	Y	4410702 <sup>2</sup>
830.1670	Discussion of formation of impurities	Y	4410702 <sup>2</sup>
830.1700	Preliminary analysis	Y	4410703 <sup>2</sup>
830.1750	Certified limits	Y	4410703 <sup>2</sup>
830.1800	Enforcement analytical method	Y	4410703 <sup>2</sup>
830.6302	Color	Y	4410704 <sup>2</sup>
830.6303	Physical state	Y	44107205 <sup>2</sup>
830.6304	Odor	Y	44107206 <sup>2</sup>
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	44134402 <sup>2</sup>
830.7000	pH	Y	44134401 <sup>2</sup>
830.7050	UV/Visible absorption	N <sup>3</sup>	
830.7200	Melting point/melting range	Y	44107207 <sup>2</sup>
830.7220	Boiling point/boiling range	N/A <sup>4</sup>	
830.7300	Density/relative density/bulk density	Y	44107208 <sup>2</sup>
830.7370	Dissociation constants in water	Y	44107210 <sup>2</sup>
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	44107211 <sup>2</sup>
830.7840	Water solubility: column elution method; shake flask method	Y	44145401 <sup>2</sup>
830.7950	Vapor pressure	Y	44107218 <sup>2</sup>

<sup>1</sup> Y = Yes; N = No; N/A = Not Applicable.

<sup>2</sup> D231609, 4/10/97, A. Smith.

<sup>3</sup> The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

<sup>4</sup> Data are not required because the TGAI is a solid at room temperature.

# IMAZALIL

## REREGISTRATION ELIGIBILITY DECISION

### RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 111901; Case 2325

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# IMAZALIL

## REREGISTRATION ELIGIBILITY DECISION

### RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 111901; Case 2325

#### INTRODUCTION

Imazalil [1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1*H*-imidazole] is a systemic fungicide registered for postharvest treatment of citrus fruits and bananas (foreign use) and for seed treatment of barley and wheat prior to planting. Imazalil's end-use products are marketed by Janssen Pharmaceutica in the United States under the trade names Fecundal® and Fungaflor®, and by Makhteshim-Agan of North America Inc. as Magnate®, all of which are emulsifiable concentrate (EC) formulations. Fungaflor® and Magnate® are also formulated as a soluble powder (SP) for use on bananas imported into the United States from Colombia, Costa Rica, Ecuador, Guatemala, Honduras, and Mexico. The reregistration of imazalil is being supported by Janssen Pharmaceutica, and by Makhteshim-Agan of North America Inc. (MANA).

#### REGULATORY BACKGROUND

The Imazalil Phase 4 Review of 10/19/90 and the subsequent Imazalil Data-Call-In (DCI) Notice of 12/31/90 summarized the status of available residue chemistry data for the reregistration of imazalil. The Phase 4 Review identified several data deficiencies including plant and livestock metabolism, residue analytical methods, storage stability, and magnitude of the residue in plants and livestock. Several studies have been submitted and evaluated in response to the Imazalil DCI. This document presents an overall and up to date Residue Chemistry Science Assessment with respect to the reregistration of imazalil.

The established tolerances for plant commodities [40 CFR §180.413(a)] are expressed in terms of the combined residues of imazalil and its metabolite R014821 [1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)-1-ethanol]. Plant commodity tolerances range from 0.05 ppm (barley grain, cottonseed, and wheat grain) to 10 ppm (citrus fruits). Tolerances are also established for the combined residues of imazalil and R014821 in citrus oil and citrus dried pulp, each at 25 ppm. The established tolerances for livestock commodities [40 CFR §180.413(b)] are expressed in terms of the combined residues of imazalil and its metabolites R014821 and R042243 [3-[1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)ethoxyl]-1,2-propanediol]. Animal commodity tolerances range from 0.01 ppm (milk and fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep) to 0.50 ppm (liver of cattle, goats, hogs, horses, and sheep). No tolerances are established for eggs or poultry tissues. Adequate GC/ECD methods are listed in the Pesticide Analytical Manual (PAM), Vol. II for enforcement of imazalil tolerances, as currently expressed. Codex

MRLs for residues of imazalil in/on plant commodities are currently defined in terms of imazalil *per se*, and as such are not compatible with U.S. tolerances.

## SUMMARY OF SCIENCE FINDINGS

### GLN 860.1200: Directions for Use

According to a REFS search, conducted on 1/22/2002, there are three active end-use products (see Table A1) registered to Janssen Pharmaceutica and Makhteshim-Agan of North America Inc. (MANA) which contain the active ingredient imazalil which is registered for use on domestically grown food/feed crops (i.e., citrus fruits, barley, and wheat). There are additional imazalil end-use products registered for use on imported bananas grown in Costa Rica, Colombia, Ecuador, Guatemala, Honduras, and Mexico. HED has examined translated imazalil foreign labels (Fungaflor® 75 SP labels) supplied by Janssen Pharmaceutica. The foreign uses were found to be adequate for the purpose of assessing whether or not the submitted banana field trial data reflect the maximum imazalil residues of concern likely to occur in/on bananas.

Table A1. Imazalil End-Use Products with Food/Feed Uses Registered to Janssen Pharmaceutica and to Makhteshim-Agan of North America Inc.

EPA Reg. No.	Label Acceptance Date	Formulation	Product Name
43813-6	9/9/85	44.6% (4.17 lb/gal) EC	Fungaflor ® 500 EC
43813-14	8/7/95	9.5% (0.84 lb/gal) EC	Fecundal ® 100 EC
66222-20	8/23/01	44.5% EC	Magnate ® 500 EC

The above labels specify a re-entry interval of 48 hours. There are no rotational crop restrictions specified on the labels. A review of the imazalil labels and supporting residue data suggest those label amendments are required to specify the number of applications for some registered crops. The 9.5% EC (EPA Reg. No. 43813-14) formulation should be amended to specify a maximum of one seed treatment prior to planting of fields with seed-treated barley and wheat. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

A comprehensive summary of imazalil food/feed use patterns, based on the product labels registered to Janssen Pharmaceutica and Makhteshim-Agan of North America Inc. (MANA), is presented in Table A2. A tabular summary of the residue chemistry science assessments for the reregistration of imazalil is presented in Table B. The status of reregistration requirements for each guideline topic listed in Table B is based on the use patterns registered by the basic producers, Janssen Pharmaceutica and Makhteshim-Agan of North America Inc. (MANA). This chapter does not include uses registered to other registrants, such as the poultry hatchery use registered to Schering-Plough (EPA Reg. No. 773-55 and 773-56) for which no residue data are available.

**Table A2. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Imazalil (Case 2325).**

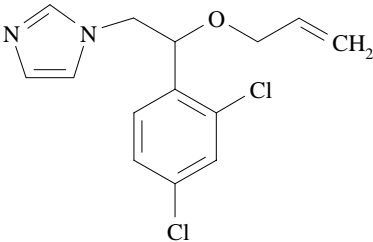
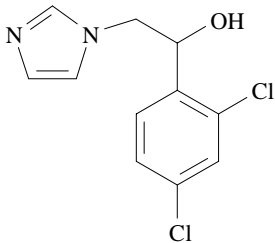
Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate	Maximum Number of Applications Per Season	Maximum Seasonal Rate	Preharvest Interval, Days	Use Directions and Limitations
<b>Bananas (Imported)</b>						
Post-harvest treatment Spray, fog, dip, or drench	Fungaflor® 75 SP (no U.S. registration)	0.07% of product in water or 525 ppm ai	1 (Implied)	525 ppm ai (Implied)	0 <sup>1</sup>	The labels recommend that “crowns and fruit need to be wetted carefully and thoroughly.” According to information provided by Janssen Pharmaceutica, spray, fog, dip, or drench application should be made for 3 to 25 seconds.
<b>Barley and Wheat</b>						
Seed treatment Mechanical slurry or mist-type of seed treatment equipment	9.5% (0.84 lb/gal) EC [43813-14]	1.5 fl. oz of product/100 lbs of seed(cwt) or 0.01 lb ai/cwt (equivalent to 100 ppm; mg ai/kg seed)	Not specified (NS)	NS	NS	Treated seeds should be adequately dyed, and any dye added to treated seeds must be cleared for use under 40 CFR §180.1001. Treated seeds should not be used for food, feed, or oil purposes. The grazing or feeding of livestock on treated areas for six weeks after planting is prohibited.
Seed treatment Mechanical slurry or mist-type of seed treatment equipment	44.5% EC [66222-20]	0.34 fl. oz of product/100 lbs of seed(cwt)	Not specified (NS)	NS	NS	Treated seeds should be adequately dyed, and any dye added to treated seeds must be cleared for use under 40 CFR §180.1001. Treated seeds should not be used for food, feed, or oil purposes. The grazing or feeding of livestock on treated areas for six weeks after planting is prohibited.
<b>Citrus Fruits</b>						
Post-harvest treatment Dips, wash tanks, and drenches	44.6% (4.17 lb/gal) EC [43813-6] and 44.5% EC [66222-20]	19.2 fl. oz of product/100 gal water or 750 ppm ai	2	4000ppm ai	Not applicable (NA)	Application should be made in dips, wash tanks, and drenchers. Length of dip time should not exceed 2 minutes.
Post-harvest treatment Wax		25.5 fl. oz of product/100 gal water or 1000 ppm ai	2 (Should not exceed 4000 ppm total) *or* 1 application of 4000ppm in wax	4000ppm ai	NA	Application should be made to freshly cleaned fruits immediately prior to waxing.
Post-harvest treatment Spray brush		25.5 fl. oz of product/100 gal water or 1000 ppm ai	2	4000ppm ai	NA	Application should be made after washing and prior to wax application.
Post-harvest treatment Foamer		51.0 fl. oz of product/100 gal water or 2000 ppm ai	2	4000ppm ai	NA	Application should be made as a ready-to-use foam detergent using a mechanical foamer.

<sup>1</sup> A 0-day PHI has been established for Costa Rica, Guatemala, Honduras, and Mexico; however, pre-harvest foliar application of imazalil is not registered for use on bananas at this time.

## GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are fulfilled. Acceptable metabolism studies, reflecting post-harvest treatment of imazalil on bananas and oranges as well as seed treatment of imazalil on wheat, were conducted. In all studies, the parent was the predominant residue identified in/on whole bananas (~ 69-82% of the total radioactive residues or TRR), banana pulps (~68-82% TRR), orange fruits (~75% TRR), wheat forage (~24% TRR), and wheat straw (~17% TRR). The total radioactivity in wheat grain, grown from wheat seeds treated with [<sup>14</sup>C] imazalil at 5x the maximum label rate, was ≤0.004 ppm and were not further characterized. The metabolite R014821 was identified as a minor component in/on banana, whole and pulp (<5% TRR), orange fruits (~3-6% TRR), wheat forage (~8% TRR), and wheat straw (~4% TRR). Several additional metabolites containing the 2,4-dichlorophenyl group were identified in analyzed commodities but they were detected at relatively low (≤5% TRR) levels. The established tolerances for plant commodities are currently expressed in terms of the combined residues of imazalil and its metabolite R014821. HED concludes that the existing tolerance expression for plant commodities is appropriate for the purpose of reregistration. The chemical structures and chemical names of these regulated compounds are depicted in Figure A.

Figure A. Chemical Names and Structures of Imazalil Residues of Concern in Plant Commodities.

Compound	Chemical Structure
<b>Common Name:</b> Imazalil <b>Janssen Research Code:</b> R023979 <b>Chemical Name:</b> 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1 <i>H</i> -imidazole	
<b>Common Name:</b> Despropenyl imazalil; ethanol metabolite <b>Metabolite Designation(s):</b> R014821; FK411 <b>Chemical Name:</b> 1-[2,4-dichlorophenyl)-2-(1 <i>H</i> -imidazole-1-yl)-1-ethanol	



#### GLN 860.1300: Nature of the Residue - Livestock

The reregistration requirements for livestock metabolism are fulfilled based on acceptable goat and poultry metabolism studies. These studies indicate that imazalil is extensively metabolized in goat and hen. Only six common metabolites (out of about twenty identified) were found in both goat and hen. Radioactive residue levels in hen eggs and tissues were <0.01 ppm (except 0.028 ppm in liver) when the exaggerated dose was taken into consideration. When normalized to the expected dietary burden, residue levels in the goat ranged from 0.015 ppm to 3.3 ppm in milk and tissues. The results of these studies were presented to the HED Metabolism Committee (L. Cheng, 8/30/94), and members of the Committee were asked whether the current tolerance expression for livestock commodities should remain unchanged or whether separate tolerance expressions should be set for ruminant and poultry, and which metabolites should require regulation in each case.

The Committee concluded that (L. Cheng, 8/30/94), in the absence of information to the contrary, any metabolite containing the 2,4-dichlorophenyl moiety is of toxicological concern, and must be included in the dietary risk assessment. The Committee also concluded that HED should define a list of metabolites containing this moiety which should be analyzed in livestock feeding studies and explicitly included in the tolerance expression. These metabolites together with the parent compound should serve as marker compounds which should, using the metabolite ratios found in the metabolism studies, be used to determine residue values for dietary risk assessment. It would be assumed that only metabolites identified in the metabolism study as having the 2,4-dichlorophenyl moiety constitute the residue to be included in risk assessment.

The registrant is now pursuing the development of a new GC/ECD method capable of quantifying residues of imazalil and appropriate marker compounds that account for a high percentage of the total toxic residues in livestock commodities; see "Residue Analytical Methods" section. The marker compounds in milk and ruminant tissues are imazalil, FK772, and FK284 which collectively represent the following percentages of the total toxic residues, as determined by the ruminant metabolism studies: 21% in milk, 72% in muscle, 71% in kidney, 44% in liver, and 33% in fat. The marker compounds in eggs and poultry tissues are imazalil, FK858, and FK326 or FK259 which collectively represent the following percentages of the total toxic residues, as determined by the poultry metabolism studies: 69% in eggs, 45% in liver, 52% in fat, and 100% in muscle. The chemical names and structures of imazalil and marker metabolites in livestock commodities are depicted in Figures B (milk and ruminant tissues) and C (eggs and poultry tissues).

Figure B. Chemical Names and Structures of Imazalil and Marker Metabolites In Milk and Ruminant Tissues.

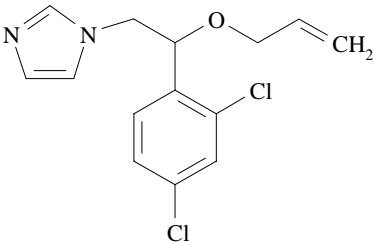
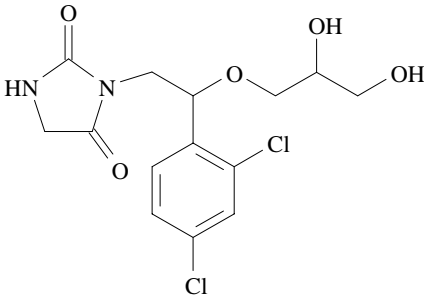
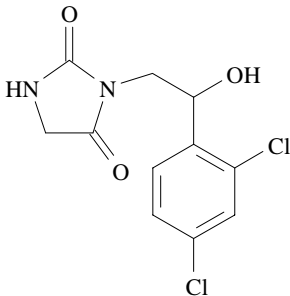
Compound	Chemical Structure
<p><b>Common Name:</b> Imazalil</p> <p><b>Janssen Research Code:</b> R023979</p> <p><b>Chemical Name:</b> 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1<i>H</i>-imidazole</p>	
<p><b>Metabolite Designation in Goat Metabolism Study:</b> FK772</p> <p><b>Janssen Research Code:</b> R061000</p> <p><b>Chemical Name:</b> 3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]-2,4-imidazolidinedione</p>	
<p><b>Metabolite Designation in Goat Metabolism Study:</b> FK284</p> <p><b>Janssen Research Code:</b> R042449 or R043449</p> <p><b>Chemical Names:</b> 3-(2-(2,4-dichlorophenyl)-2-(hydroxy)-2,4-imidazolidinedione  or  1-[2-(2,4-dichlorophenyl)-2-hydroxyethyl]-2,4-imidazolidinedione</p>	

Figure C. Chemical Names and Structures of Imazalil and Marker Metabolites In Eggs and Poultry Tissues.

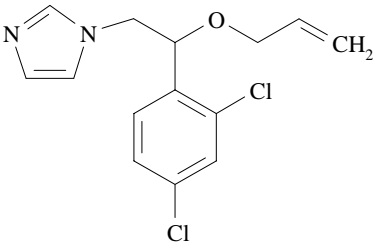
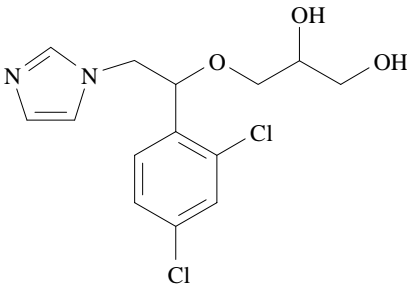
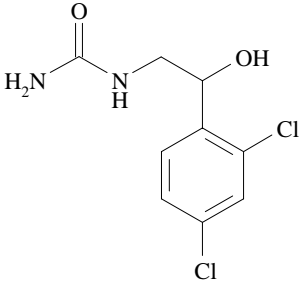
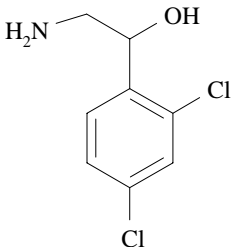
Compound	Chemical Structure
<p><b>Common Name:</b> Imazalil</p> <p><b>Janssen Research Code:</b> R023979</p> <p><b>Chemical Name:</b> 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1<i>H</i>-imidazole</p>	
<p><b>Metabolite Designation in Poultry Metabolism Study:</b> FK858</p> <p><b>Janssen Research Code:</b> R042639 or bishydroxylated imazalil</p> <p><b>Chemical Names:</b> 3-[1-(2,4-dichlorophenyl)-2-(1<i>H</i>-imidazole-1-yl)ethoxy]-1,2-propanediol or 1-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]-1<i>H</i>-imidazole</p>	
<p><b>Metabolite Designation in Poultry Metabolism Study:</b> FK326</p> <p><b>Janssen Research Code:</b> R044085</p> <p><b>Chemical Name:</b> (±)-N-[2-(2,4-dichlorophenyl)-2-hydroxyethyl]urea</p>	

Figure C (continued).

Compound	Chemical Structure
<b>Metabolite Designation in Poultry Metabolism Study:</b> FK259 <b>Janssen Research Code:</b> R018238 <b>Chemical Name:</b> 1-(2,4-dichlorophenyl)-2-aminoethanol	
	

#### GLN 860.1340: Residue Analytical Methods

An adequate residue analytical method is available for determining the total toxic residues of imazalil in/on plant commodities but not in livestock commodities.

*Method for determination of residues in/on plant commodities:* The Pesticide Analytical Manual (PAM) Volume II lists a GC/ECD method, designated as Method I, for the quantitation of residues of imazalil and its metabolite R014821 in/on bananas, citrus fruits, cottonseed, and small grains. Briefly, residues are extracted from plant samples with heptane:isoamyl alcohol (95:5, v:v), partitioned into 0.1 N H<sub>2</sub>SO<sub>4</sub>, and re-extracted from alkaline solution into heptane:isoamyl alcohol (95:5, v:v). The extract is evaporated to dryness, and N, O-bis(trimethylsilyl)acetamide is added to convert the metabolite to the trimethylsilyl derivative. Imazalil and the derivatized metabolite are determined separately by GC with electron capture detection from a single injection of the derivative solution. The limits of detection range from 0.01-0.05 ppm, depending on the plant matrix. Plant commodity samples collected from studies pertaining to magnitude of the residues in plant were analyzed for residues of imazalil and its metabolite R014821 using this PAM Volume II method or its modification; in these field studies, method recoveries obtained from concurrent analyses of treated samples were acceptable. This enforcement method has been adequately radio-validated using samples from the banana metabolism study.

*Methods for determination of residues in livestock commodities:* The PAM Volume II also lists a GC/ECD method, designated as Method II, for the quantitation of residues of imazalil and the metabolites R014821 and R042243. The limits of detection range from 0.01 to 0.05 ppm, depending on the specific matrix. Method II also involves the conversion of the metabolites to the trimethylsilyl derivatives and separate determination of imazalil and the derivatized metabolites. It should be noted that this method is not a precise measure of the total toxic imazalil residues in meat, milk, poultry, and eggs, as determined by the results of livestock metabolism studies.

Because of the recommended changes in tolerance expression, a new enforcement method capable of determining imazalil and any metabolite containing the 2,4-dichlorophenyl group in livestock commodities is required. To accomplish this, HED suggested that the registrant develop an enforcement method capable of measuring all compounds containing the 2,4-dichlorophenyl group using a method which converts these residues to a common moiety. Alternatively, the registrant was given the option of developing an enforcement method for a set of marker compounds that account for a high percentage of the total toxic residues in ruminant and poultry.

Attempts by the registrant to develop a common moiety method, based on the oxidation of imazalil and five of its metabolites to 2,4-dichlorobenzoic acid, were unsuccessful due to extraction inefficiency and method recovery variability. The registrant is now pursuing the development of a new GC/ECD method capable of quantitating residues of imazalil and the appropriate marker metabolites. Preliminary validation data indicate that the proposed GC/ECD method is adequate for collecting data on residues of imazalil, FK772, and FK284 in milk and ruminant tissues, provided fortified control samples are analyzed concurrently with each set of treated samples to assure that acceptable method recoveries are being achieved for each analysis; independent laboratory validation must be conducted prior to the method being sent to the Agency for validation as an enforcement method. This method was used in the analysis of samples collected from a recently reviewed ruminant feeding study.

For the purpose of reregistration, the registrant must continue to develop/validate enforcement method(s) for a set of marker compounds that account for a high percentage of the total toxic residues in ruminant and poultry. HED will correct residues to account for the total toxic residue for the purpose of tolerance reassessment as well as for dietary risk exposure assessment.

#### GLN 860.1360: Multiresidue Methods

The 2/97 FDA PESTDATA database (PAM Volume I, Appendix) indicates that the parent imazalil is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method; Protocol D) but is not recovered using Multiresidue Methods Sections 303 (Mills, Onley, and Gaither; Protocol E, nonfatty) and 304 (Mills, fatty food).

Multiresidue methods data have not been submitted for imazalil metabolites that warrant inclusion in the tolerance expression. To fully satisfy reregistration requirements, the following metabolites must be tested through FDA's multiresidue protocols: (i) metabolite R014821; (ii) marker metabolites in milk and ruminant tissues (FK772 and FK284); and (iii) marker metabolites in eggs and poultry tissues (FK858, and FK326 or FK259). The registrant is required to follow the directions for the protocols found in PAM Volume I, Appendix II starting with the decision tree for multiresidue methods testing and the accompanying guidance found in the suggestions for producing quality data; i.e. decisions on what protocols to follow and proper application of methods. If the decision tree indicates that recovery is likely, the registrant should consult the data development section of the proper protocols and follow the guidance offered precisely to generate quality data.

#### GLN 860.1380: Storage Stability Data

The reregistration requirements for storage stability data are satisfied. Adequate storage stability data for plant and livestock commodities have been submitted and evaluated.

*Plant commodities:* Several storage stability studies have been submitted and evaluated. These studies showed that residues of imazalil and its metabolite R014821 are stable under frozen storage conditions in/on: (I) bananas for up to 38 weeks; (ii) citrus fruits and their processed commodities for up to 34 weeks; and (iii) wheat grain and forage for up to 24 weeks. These storage stability data are adequate to validate the storage intervals and conditions of samples collected from respective field and processing studies. It should be noted that HED previously concluded that residues of imazalil and its metabolite R014821 can decline significantly in/on wheat straw (~30-40%) over relatively short (~12-24 weeks) periods of time. However, reanalysis of treated wheat grain and straw samples collected during field trials indicate that residues are stable in these wheat RACs for at least 300 days.

*Livestock commodities:* Storage stability data, submitted in support of the goat metabolism study, are adequate and indicate that radioactive residues of imazalil in the aqueous extracts of milk, liver, and kidney are stable under frozen storage conditions for up to 15 months. No storage stability data were submitted in support of the hen metabolism study; however, analysis of egg and tissue samples collected from the hen metabolism study were completed within six months of sampling. Samples collected from the ruminant feeding studies were stored frozen for 30 days prior to residue analysis.

#### GLN 860.1400: Water, Fish, and Irrigated Crops

Imazalil is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

#### GLN 860.1460: Food Handling

Imazalil is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

#### GLN 860.1480: Meat, Milk, Poultry, Eggs

*Ruminants:* The reregistration requirements for data depicting the magnitude of imazalil residues of concern in milk and tissues of ruminants are fulfilled. An acceptable ruminant feeding study has been submitted and the maximum theoretical dietary intake of imazalil derived from existing or proposed tolerances has been calculated. As determined by HED, the beef and dairy cattle diets consisting of citrus pulp, wheat straw, wheat grain, and wheat forage would result in burdens of about 6.7 ppm and 4.7 ppm in the diets of dairy cattle and beef cattle, respectively.

In the ruminant feeding study, dairy cows were fed imazalil placed into gelatin capsules and administered by balling gun twice daily for 28 consecutive days at feeding levels of 33 ppm, 99 ppm, and 330 ppm. At the feeding level of 33 ppm, the maximum combined residues of imazalil and the marker metabolites FK772 and FK284 were 0.054 ppm in milk, 0.050 ppm in muscle, 0.956 ppm in liver, 0.155 ppm in kidney, and 0.026 ppm in fat. Presently the dietary burden does not contain wet apple pomace as the previous chemistry chapter did. The Chemistry files indicate the apple tolerance petition was withdrawn by the registrant. The 33 ppm feeding level is now 5x and 7x the dairy and beef cattle dietary burden, respectively. The reassessed tolerances for livestock commodities are presented in Table C.

*Hogs/Horses*: Secondary residues of imazalil in hog and horse (fat) fall under CFR 180.6 (a)(3), since there is no reasonable expectation of finite residues. There is no reasonable expectation of residues because guidance does not support hogs feeding on citrus dried, pulp and therefore tolerances are recommended to be revoked.

Maximum residues of imazalil in the diet of dairy cattle				
Feed Item	Proposed Tolerance (ppm)	% Dry Matter	% Livestock Diet	Dietary Burden (ppm)
protein source (soybeans)	na	na	20	0
citrus pulp, dried	25	91	20	5.5
wheat forage	0.5	25	60	1.2
<b>TOTAL</b>			<b>100</b>	<b>6.7</b>

Maximum residues of imazalil in the diet of beef cattle				
Feed Item	Proposed Tolerance (ppm)	% Dry Matter	% Livestock Diet	Dietary Burden (ppm)
citrus pulp, dried	25	91	15	4.1
protein source (soybeans)	na	na	20	0
wheat forage	0.5	25	20	0.4
wheat straw	0.5	88	30	0.18
wheat grain	0.05	89	15	0.01
<b>TOTAL</b>			<b>100</b>	<b>4.7</b>

**Residues of Imazalil and its Metabolites in Raw Milk from Cows Fed Imazalil for 28 Days.**

Imazalil Feeding Concentration (ppm)	Milk Sampling Day	Imazalil Range (ppm)	FK772 ref. B	FK284 ref. C	Total Residue Range (ppm)
330 ppm (49x)	1	0.010- 0.029	0.013- 0.020	0.017- 0.063	0.040- 0.112
	3	0.092- 0.158	0.021- 0.031	0.166- 0.209	0.279- 0.298
	7	0.067- 0.078	0.041- 0.055	0.134- 0.180	0.242- 0.313
	15	0.042- 0.057	0.033- 0.049	0.092- 0.167	0.167- 0.273
	22	0.025- 0.028	0.026- 0.030	0.086- 0.127	0.137- 0.185
	28	0.002- 0.016	0.017- 0.020	0.053- 0.084	0.072- 0.120
99 ppm (15x)	1	0.003- 0.012	0.002- 0.004	0.002- 0.008	0.007- 0.024
	3	0.011- 0.031	0.011- 0.013	0.024- 0.049	0.046- 0.093
	7	0.013- 0.021	0.016- 0.017	0.030- 0.033	0.059- 0.071
	13	0.007- 0.009	0.006- 0.008	0.020- 0.032	0.033- 0.049
	20	0.006- 0.007	0.011- 0.017	0.010- 0.017	0.027- 0.041
	28	0.000- 0.005	0.015- 0.021	0.013- 0.028	0.028- 0.054
33 ppm (5x)	1	0.011- 0.015	0.002- 0.003	0.000- 0.001	0.013- 0.019
	3	0.008- 0.013	0.007- 0.010	0.000- 0.001	0.015- 0.024
	7	0.007- 0.017	0.002- 0.005	0.004- 0.007	0.013- 0.029
	14	0.006- 0.010	0.002- 0.004	0.001- 0.006	0.009- 0.020
	21	0.005- 0.007	0.007- 0.008	0.003- 0.005	0.015- 0.020
	28	0.005- 0.016	0.002- 0.021	0.008- 0.017	0.015- 0.054

**Residues of Imazalil and its Metabolites in Ruminant Tissues from Cows Fed Imazalil for 28 Days.**

Imazalil Feeding Concentration (ppm)	Tissue	Imazalil Range (ppm)	Ref.B (FK 772)	Ref. C (FK284)	Total Residue Range (ppm)
330 ppm (70x)	Muscle	0.003- 0.023	0.015- 0.071	0.074- 0.105	0.092- 0.199
	Liver	7.534- 12.253	0.622- 0.895	0.816- 1.535	8.972- 14.683
	Kidney	0.606- 1.453	0.633- 1.298	0.355- 1.076	1.594- 3.827
	Fat	0.067- 0.224	0.032- 0.043	0.014- 0.083	0.113- 0.350



Imazalil Feeding Concentration (ppm)	Tissue	Imazalil Range (ppm)	Ref.B (FK 772)	Ref. C (FK284)	Total Residue Range (ppm)
99 ppm (21x)	Muscle	0.000- 0.017	0.005- 0.017	0.017- 0.043	0.022- 0.077
	Liver	1.380- 2.759	0.164- 0.514	0.165- 0.440	1.709- 3.713
	Kidney	0.153- 0.271	0.191- 0.285	0.038- 0.072	0.382- 0.628
	Fat	0.004- 0.014	0.004- 0.032	0.002- 0.021	0.010- 0.067
33 ppm (7x)	Muscle	0.001- 0.014	0.002- 0.014	0.000- 0.022	0.003- 0.050
	Liver	0.142- 0.506	0.072- 0.229	0.107- 0.221	0.321- 0.956
	Kidney	0.006- 0.035	0.055- 0.090	0.000- 0.030	0.061- 0.155
	Fat	0.000- 0.014	0.000- 0.007	0.000- 0.005	0.000- 0.026

*Poultry:* HED has made a determination to not require tolerances for imazalil residues of concern in eggs and poultry tissues since there is no reasonable expectation of finite residues [40 CFR §180.6(a)(3)]. This determination is based on a review of a poultry feeding study (DP barcode D254805, D. Hrady, 1/19/00.) However, a determination of tolerances resulting from a fumigation application has not yet been made and remains a data gap (see 773-EUP-R, memo of 8/12/85, A. Reiter and S. Hummel).

#### GLN 860.1500: Crop Field Trials

The reregistration requirements for data depicting the magnitude of imazalil and its metabolite R014821 in/on the following raw agricultural commodities (RACs) are fulfilled: bananas, barley grain, barley straw, citrus fruits, wheat grain, wheat forage, and wheat straw. Except for the grains of barley and wheat, the available crop field trials reflecting use of registered formulations at 1x the maximum label rate showed finite residues of imazalil and its metabolite R014821 in/on the RACs of crops for which registration exists.

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). Table 1 now lists hay as a RAC of barley, and barley forage was removed as a RAC. No data for barley hay have been submitted. However, the available data for barley forage and straw will be translated to barley hay.

Table 1 also lists wheat hay as a RAC of wheat, and no data for wheat hay have been submitted. The available data for wheat forage and straw will be translated to wheat hay. Residue data for wheat aspirated grain fractions are not required because imazalil's registered use on wheat is limited to seed treatment, which typically does not trigger data requirement for aspirated grain fractions.

There are no registered uses of imazalil on cottonseed for which a tolerance is established. To date, no registrants have committed to support imazalil use on cottonseed. Unless, Janssen Pharmaceutica or other registrants submit supporting residue data, HED will recommend for tolerance revocation.

#### GLN 860.1520: Processed Food/Feed

The reregistration requirements for studies pertaining to the magnitude of the residue in the processed commodities of citrus fruits are fulfilled. Acceptable citrus processing studies, reflecting post-harvest treatments and conducted according to commercial practice, were separately conducted on grapefruit, oranges, and lemons. Citrus fruits were treated with imazalil in a wax formulation at 1x and 2x the maximum registered label rates. The studies showed that residues of imazalil and its metabolite R014821 do not concentrate in juice; the combined residues reduced by ~90% in citrus juice. However, residues of imazalil and its metabolite R014821 do concentrate in dried pulp and oil. In dried pulp, the maximum average concentration factor of total residues in oranges was 2.5x; the overall average concentration factor of total residues for the three citrus crops was 1.7x. In oil, the average concentration of total residues was 3.3x in lemon, 15.0x in grapefruit, and 28.0x in oranges; the overall average concentration factor in oil for the three citrus crops was 16.0x. Refer to “Tolerance Reassessment Summary” section for recommendations with respect to the need for tolerances as a result of concentration of residues in citrus processed commodities.

HED has earlier concluded that barley and wheat grain processing studies are not required. This determination was based on the theoretical concentration factors for barley and wheat grain processed commodities (1.2-9x), the apparent residues <LOQ from the use of exaggerated application rates (6.3x and 10x), and the use pattern (seed treatment), which is unlikely to result in surface residues on the grain. The combined residues of imazalil and its metabolite R014821 in/on barley and wheat processed commodities are not likely to exceed the reassessed tolerances for barley and wheat grains.

#### GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

Confined and/or field accumulation studies are not required because the use of imazalil on annual crops (represented by barley and wheat) eligible for reregistration is limited to seed treatment prior to crop planting. Furthermore, the available plant metabolism data indicate that the total radioactivity in wheat grain, grown from wheat seeds treated with [<sup>14</sup>C] imazalil at 5x the maximum label rate, was ≤0.004 ppm. HED does not anticipate uptake of imazalil residues of concern in/on rotational crops when registered formulations of imazalil are applied to primary crops according to the maximum registered use patterns. No specific rotational crop restrictions should be imposed at this time.

#### **Table B. Residue Chemistry Science Assessments for Reregistration of Imazalil.**

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
860.1200: Directions for Use	Not applicable (N/A)	Yes <sup>2</sup>	See Tables A1 and A2
860.1300: Plant Metabolism	N/A	No	<b>00027532, 00087542, 00087543, 00096418, 00157188</b> , 42012006 <sup>3</sup> , 42012007 <sup>3</sup> , 42012008 <sup>4</sup> , 42012009 <sup>4</sup> , 42403102 <sup>5</sup> , 42626901 <sup>6</sup> , 43308401 <sup>7</sup> , 43965701 <sup>8</sup> , <b>92072019, 92072020, 92072035, 92072036, 92072037</b>
860.1300: Livestock Metabolism	N/A	No	<b>00027533, 00084644</b> , 42012005 <sup>3</sup> , 42454801 <sup>9</sup> , 42454802 <sup>9</sup> , 42593602 <sup>9</sup> , 42838201 <sup>10</sup> , 42949401 <sup>11</sup> , 43076101 <sup>12</sup> , <b>92072021, 92072038</b>
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	<b>00109269, 00127900</b> , 42454803 <sup>13</sup> , 42454804 <sup>13</sup> , 42454805 <sup>13</sup> , 42626902 <sup>6</sup> , 44532901 <sup>14</sup> , <b>92072022, 92072023</b>
- Livestock commodities	N/A	Yes <sup>15</sup>	<b>00109269</b> , 44337701 <sup>16</sup> , 44455601 <sup>17</sup> , <b>92072024</b>
860.1360: Multiresidue Methods	N/A	Yes <sup>18</sup>	FDA PESTDATA database (PAM Volume I, Appendix)
860.1380: Storage Stability Data			
- Plant/processed commodities	N/A	No	<b>00157189</b> , 42626903 <sup>6</sup> , 42643301 <sup>19</sup> , 42755301 <sup>20</sup> , <b>92072025</b>
- Livestock commodities	N/A	No	42838201 <sup>10</sup>
860.1500: Crop Field Trials			
<u>Citrus Fruits Group</u>	10.0 [§180.413(a)]	No	<b>40509402, 40509403, 92072027</b> , 92072030 <sup>21</sup> , 92072040 <sup>21</sup>
<u>Cereal Grains Group</u>			
- Barley, grain	0.05 [§180.413(a)]	No	<b>00127900, 00150020, 00157190</b> , 42852001 <sup>22</sup> , <b>92072026, 92072042</b>
- Wheat, grain and aspirated grain fractions	0.05 [§180.413(a)]	No <sup>23</sup>	<b>00127900, 00157190</b> , 42852002 <sup>22</sup> , 42868101 <sup>22</sup> , 43285001 <sup>24</sup> , <b>92072029, 920722041</b>
<u>Fodder, Forage, Hay, and Straw of Cereal Grains Group</u>			

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
- Barley, hay and straw	0.5, forage and straw [§180.413(a)]	No <sup>25</sup>	<b>00127900, 00150020,</b> <b>00157190, 42852001 <sup>22</sup>, 92072026,</b> <b>92072042</b>
- Wheat, forage, hay, and straw	0.5, forage and straw [§180.413(a)]	No <sup>26</sup>	<b>00127900, 00157190, 42852002 <sup>22</sup>,</b> <b>42868101 <sup>22</sup>, 43285001 <sup>24</sup>,</b> <b>92072029, 920722041</b>
<u>Miscellaneous Commodities</u>			
- Bananas	3.0, whole; 0.2, pulp [§180.413(a)]	No	42058701 <sup>27</sup> , 42710501 <sup>28</sup>
- Cotton, seed and gin byproducts	0.05, cottonseed [§180.413(a)]	No <sup>29</sup>	<b>00127900, 92072028, 92072039</b>
860.1520: Processed Food/Feed			
- Barley	0.05, grain [§180.413(a)]	No <sup>30</sup>	
- Citrus	10.0, citrus fruits [§180.413(a)]; 25.0, citrus oil [§185.3650]; 25.0, citrus dried pulp [§186.3650]	No	<b>40509403, 42348301 <sup>31</sup>, 42405501</b> <b><sup>31</sup>, 42454806 <sup>32</sup>, 92072040 <sup>21</sup></b>
- Wheat	0.05, grain [§180.413(a)]	No <sup>30</sup>	
860.1480: Meat, Milk, Poultry, Eggs			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.01, milk, fat, meat, mbyp; 0.5, liver [§180.413(b)]	No	<b>00079192, 00079193, 00109269,</b> <b>44568301 <sup>33</sup></b>
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	§180.6(a)3	Yes <sup>34</sup>	
860.1400: Water, Fish, and Irrigated Crops			
	N/A	N/A	
860.1460: Food Handling			
	N/A	N/A	
860.1850: Confined Rotational Crops			
	N/A	No	
860.1900: Field Rotational Crops			
	None established	No	

Table B (*continued*).

1. **Bolded** references were evaluated in the Imazalil Phase 4 Review (S. Funk, 10/19/90). All other references were reviewed as noted.
2. The 9.5% EC (EPA Reg. No. 43813-14) formulation of imazalil should be amended to specify a maximum of one seed treatment prior to planting of fields with seed-treated barley and wheat.
3. DP Barcode D171401, 2/4/92, L. Cheng.
4. DP Barcode D198235, 5/3/94, L. Cheng.
5. DP Barcode D181284, 9/25/92, L. Cheng.
6. DP Barcode D187506, 1/10/94, L. Cheng.
7. DP Barcode D205954, 9/22/94, L. Cheng.
8. DP Barcode D224876, 6/12/96, L. Cheng.
9. DP Barcodes D182706 and D186541, 2/17/93, J. Abbotts.
10. DP Barcode D193375, 8/17/93, J. Abbotts.
11. DP Barcode D195726, 11/17/93, S. Funk.
12. DP Barcode D198599, 7/14/94, L. Cheng.
13. DP Barcode D182707, 6/24/93, S. Funk.
14. DP Barcode 245510, 1/19/00, D. Hrdy.
15. Because of the recommended changes in tolerance expression, a new enforcement method capable of determining imazalil and any metabolite containing the 2,4-dichlorophenyl group in livestock commodities is required. The registrant must continue to develop/validate enforcement method(s) for a set of marker compounds that account for a high percentage of the total toxic residues in ruminant. HED will correct residues to account for the total toxic residue for the purpose of tolerance reassessment as well as for assessing dietary risk exposure.
16. DP Barcode D238452, 1/20/99, S. Piper.
17. DP Barcode D242498 (currently under secondary review at HED).
18. The following metabolites must be tested through FDA's multiresidue protocols: (i) metabolite R014821; (ii) marker metabolites in milk and ruminant tissues (FK772 and FK284). The registrant is required to follow the directions for the protocols found in PAM Volume I, Appendix II starting with the decision tree for multiresidue methods testing and the accompanying guidance found in the suggestions for producing quality data; i.e. decisions on what protocols to follow and proper application of methods. If the decision tree indicates that recovery is likely, the registrant should consult the data development section of the proper protocols and follow the guidance offered precisely to generate quality data.

Table B (*continued*).

19. DP Barcode D187775, 3/2/93, S. Funk.
20. DP Barcode D191318, 11/18/93, D. Miller.
21. DP Barcode D220386, 5/8/96, S. Funk.
22. DP Barcode D194151, 12/21/93, S. Funk.
23. Adequate residue data have been submitted for wheat grain. Residue data for wheat aspirated grain fractions are not required because imazalil's registered use on wheat is limited to seed treatment.
24. DP Barcode D205092, 1/20/95, L. Cheng.
25. Adequate residue data have been submitted for barley straw. Table 1 of OPPTS GLN 860.1000 now lists hay as a RAC of barley, but forage was removed from the list. No data for barley hay have been submitted. The available data for barley forage and straw will be translated to barley hay.
26. Adequate residue data have been submitted for wheat forage and straw. Table 1 of OPPTS GLN 860.1000 now lists hay as a RAC of wheat, and no data for wheat hay have been submitted. The available data for wheat forage and straw will be translated to wheat hay.
27. DP Barcode D170886, 8/13/92, A. Aikens.
28. DP Barcode D189963, 7/14/94, L. Cheng.
29. There are no registered uses of imazalil on cottonseed for which a tolerance is established. To date, no registrants have committed to support imazalil use on cottonseed. Unless Janssen Pharmaceutica or other registrants submit supporting residue data, HED will recommend for tolerance revocation.
30. The requirements for barley and wheat processing studies are waived based on the theoretical concentration factors for barley and wheat grain processed commodities (1.2-9x), on apparent residues <LOQ from the use of exaggerated application rates (6.3x and 10x), and on the use pattern (seed treatment), which is unlikely to result in surface residues on the grain. The combined residues of imazalil and its metabolite R014821 in/on barley and wheat processed commodities are not likely to exceed the reassessed tolerance of barley and wheat grains.
31. DP Barcode D181319, 9/3/92, S. Funk.
32. DP Barcode D182575, 2/17/93, S. Funk.
33. DP Barcode D244510, 1/22/99, S. Piper.
34. A determination of tolerances resulting from a fumigation application has not yet been made. Residue data for this use remains a data gap (see 773-EUP-R, memo of 8/12/85, A. Reiter and S. Hummel).

## TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues in/on *plant commodities* are established under 40 CFR §180.413(a). They are currently expressed in terms of the combined residues of imazalil [1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1*H*-imidazole] and its metabolite R014821 [1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)-1-ethanol]. The qualitative nature of the residue in plants is adequately understood. HED has determined that the current tolerance expression for plant commodities is appropriate.

Tolerances for residues in *livestock commodities* are established under 40 CFR §180.413(b). They are currently expressed in terms of the combined residues of imazalil and its metabolites R014821 and R042243 [3-[1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)ethoxyl]-1,2-propanediol]. The qualitative nature of the residue in livestock is adequately understood. The HED Metabolism Committee concluded that, in the absence of information to the contrary, any metabolite containing the 2,4-dichlorophenyl moiety is of toxicological concern and must be included in the conduct of the dietary risk assessment but a list of marker metabolites in addition to imazalil should be defined for inclusion in the tolerance expression (L. Cheng, 8/30/94).

The tolerance expression for livestock commodities listed under 40 CFR §180.413(b) should be amended to regulate imazalil, 3-[2-(2,4-dichlorophenyl)-2-(2,3-dihydroxypropoxy)ethyl]-2,4-imidazolidinedione (FK772), and 3-[2-(2,4-dichlorophenyl)-2-(hydroxy)]-2,4-imidazolidinedione (FK284). Because of issues related to residue analytical methods, HED hereby defines a list of marker metabolites representing the 2,4-dichlorophenyl group moiety. For dietary assessment, the total toxic residues will be adjusted using the ratios of imazalil and the marker metabolites that were found in the livestock metabolism studies. The marker compounds in milk and ruminant tissues are imazalil, FK772, and FK284; these marker compounds collectively represent the following percentages of the total toxic residues, as determined by the ruminant metabolism studies: 21% in milk, 72% in muscle, 71% in kidney, 44% in liver, and 33% in fat. The chemical names and structures of these marker metabolites are depicted in Figure B.

A summary of imazalil tolerance reassessments is presented in Table C. The reassessments of tolerances for some commodities are contingent upon the implementation of the requested label revision.

#### Tolerances Established Under 40 CFR §180.413(a)

Sufficient field trial data reflecting the maximum label use pattern are available to reassess the established tolerances for the following RACs **as defined**: bananas (whole); bananas (pulp); barley, forage; barley, grain; barley straw; citrus fruits (POST-H); wheat, forage; wheat, grain; and wheat, straw.

The established tolerances listed under 40 CFR §180.413(a) are reassessed at the same levels except those listed for the grains of barley and wheat. Higher tolerances are required for barley and wheat grains, from 0.05 ppm to 0.1 ppm, to reflect the sensitivity of the data-collection method and to account for apparent residues in/on control grain samples.

Acceptable citrus processing studies, reflecting postharvest treatments, have been submitted and evaluated. The data from these studies showed that residues of imazalil and its metabolite R014821 do not concentrate in juice but do concentrate in oil. In oil, the average concentration of total residues was 3.3x in lemon, 15.0x in grapefruit, and 28.0x in oranges; the overall average concentration factor in oil for the three citrus crops was 16.0x. These processing data suggest that a tolerance for juice is not needed, and that the established tolerance of 25 ppm for citrus oil is too low. The maximum combined residues of imazalil and its metabolite R014821 expected in citrus oil, based on the HAFT residue for oranges (6.68 ppm) and the maximum average concentration factor for oranges (28.0x) would be 187 ppm. The reassessed tolerance for citrus oil is, therefore, 200 ppm.

The available citrus processing studies reflecting postharvest treatments showed that residues of imazalil and its metabolite R014821 concentrated marginally in dried pulp. The maximum average concentration factor of total residues in orange dried pulp was 2.5x; the overall average concentration factor of total residues in citrus dried pulp was 1.7x. These processing data suggest that the established tolerance of 25 ppm for dried pulp is adequate. The maximum combined residues of imazalil and its metabolite R014821 expected in citrus dried pulp, based on the HAFT residue for oranges (6.68 ppm) and the maximum average concentration factor for oranges (2.5x) would be 16.7 ppm.

The reregistration requirements for barley and wheat grain processing studies have been waived. Therefore, tolerances for the processed commodities of barley and wheat are not required.

The established tolerance for banana pulp should be revoked since it is the Agency policy to establish a tolerance on the whole commodity (including peel after removing and discarding crown tissue and stalk). The available data on banana pulp may be used for the purpose of dietary risk assessment.

The established tolerance for cottonseed should be revoked because there are no registered uses of imazalil on cottonseed, and no registrants have committed to support imazalil use on cotton.

#### Tolerances To Be Proposed Under 40 CFR §180.413(a)



Tolerances for barley hay and wheat hay must be proposed. The available data for barley forage and straw will be translated to barley hay. The available data for wheat forage and straw will be translated to wheat hay. A tolerance of 0.5 ppm is recommended for both barley and wheat hay.

#### Tolerances Established Under 40 CFR §180.413(b)

An acceptable ruminant feeding study has been submitted and evaluated. At the feeding level of 33 ppm, the maximum combined residues of imazalil and the marker metabolites (FK772 and FK284) were 0.054 ppm in milk, 0.050 ppm in muscle, 0.956 ppm in liver, 0.155 ppm in kidney, and 0.026 ppm in fat.

The reassessed tolerances are 0.02 ppm for milk, 0.02 ppm for muscle of cattle, goats, horses, and sheep; 0.01 ppm for fat of cattle, goats, and sheep; 0.20 ppm for mbyp (meat by-products) of cattle, goats, horses, and sheep; and 0.20 ppm for liver of cattle, goats, horses, and sheep.

A poultry feeding study was required to determine whether tolerances would be required for imazalil residues of concern in eggs and poultry tissues. There is no reasonable expectation of finite residues [40 CFR §180.6(a)(3)]. However, a determination of tolerances resulting from a fumigation application has not yet been made and remains a data gap (see 773-EUP-R, memo of 8/12/85, A. Reiter and S. Hummel.)

#### Pending Tolerance Petitions

PP#4F3096: Janssen Pharmaceutica had originally proposed in a petition, FAP 4H5434, the establishment of tolerances for residues of imazalil and its metabolite R014821 [1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)-1-ethanol] in/on the pome fruit group at 7.0 ppm and in wet/dry apple pomace at 30 ppm. The petitioner subsequently withdrew FAP 4H5434 and revised PP#4F3096, for the establishment of a tolerance on pear at 10 ppm. Following review of the proposed uses and residue data, HED recommended for the establishment of a tolerance on pear at 10 ppm (DP Barcode D197176, 6/2/94, M.I. Rodriguez). Janssen Pharmaceutica proposed in a separate petition, PP#7F3530, for tolerances on melons (excluding watermelon) by post-harvest application and sweet corn by seed treatment.

Table C. Tolerance Reassessment Summary for Imazalil.

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
<b>Tolerances Established Under 40 CFR §180.413(a)</b>			
Bananas (Whole)	3.00	3.0	The tolerance for banana pulp should be revoked because it is the Agency policy to establish a tolerance on the whole commodity (including peel after removing and discarding crown tissue and stalk). The available data on banana pulp may be used for the purpose of dietary risk assessment.
Bananas (Pulp)	0.20	Revoke	
Barley, forage	0.5	Revoke	This RAC has been deleted from Table 1 of OPPTS GLN 860.1000.
Barley, grain	0.05	0.1	A higher tolerance is needed to reflect the sensitivity of the data-collection method and to account for apparent residues in/on control grain samples.
Barley, straw	0.5	0.5	
Citrus fruit (POST-H)	10.0	10.0	
Citrus oil	25.0	200	
Citrus pulp (dried)	25.0	25	
Cottonseed	0.05	Revoke	The tolerance should be revoked because there are no registered uses of imazalil on cottonseed, and no registrants have committed to support imazalil use on cottonseed.
Wheat, forage	0.5	0.5	
Wheat, grain	0.05	0.1	A higher tolerance is needed to reflect the sensitivity of the data-collection method and to account for apparent residues in/on control grain samples.
Wheat, straw	0.5	0.5	
<b>Tolerances To Be Proposed Under 40 CFR §180.413(a)</b>			
Barley, hay	None established	0.5	The available data for barley forage and straw will be translated to barley hay.
Wheat, hay	None established	0.5	The available data for wheat forage and straw will be translated to wheat hay.
<b>Tolerances Established Under 40 CFR §180.413(b)</b>			
Cattle, fat	0.01	0.01	
Cattle, liver	0.50	0.20	
Cattle, meat	0.01	0.02	
Cattle, mbyp	0.01	0.20	
Goats, fat	0.01	0.01	
Goats, liver	0.50	0.2	
Goats, meat	0.01	0.02	
Goats, mbyp	0.01	0.20	
Hogs, fat	0.01	Revoke	§180.6(a)3
Hogs, liver	0.50	Revoke	§180.6(a)3
Hogs, meat	0.01	Revoke	§180.6(a)3
Hogs, mbyp	0.01	Revoke	§180.6(a)3
Horses, fat	0.01	Revoke	§180.6(a)3
Horses, liver	0.50	0.20	
Horses, meat	0.01	0.02	
Horses, mbyp	0.01	0.20	

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment <i>[Correct Commodity Definition]</i>
Milk	0.01	0.02	
Sheep, fat	0.01	0.01	
Sheep, liver	0.50	0.20	
Sheep, meat	0.01	0.02	
Sheep, mbyp	0.01	0.20	

However, a determination of tolerances resulting from a fumigation application has not yet been made and remains a data gap (see 773-EUP-R, memo of 8/12/85, A. Reiter and S. Hummel).

## CODEX HARMONIZATION

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for imazalil in/on various raw agricultural commodities. The Codex MRLs are expressed in terms of imazalil *per se*. The Codex MRLs and the U.S. tolerances are incompatible with respect to tolerance expression. The U.S. tolerances for plant commodities are expressed in terms of the combined residues of imazalil and its metabolite R014821. The expression of U.S. tolerances for livestock commodities will be amended to include imazalil, marker metabolite FK772, and marker metabolite FK284. Both Codex and U.S. have established MRLs/tolerances for bananas, citrus fruits, and wheat grain, forage, hay, and straw. However, the residue levels are not in harmony presumably because of differences in good agricultural practices. A numerical comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances is presented in Table D.

Table D. Codex MRLs for Imazalil and applicable U.S. tolerances.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Banana	2 Po <sup>a</sup>	CXL	3.0	
Citrus fruits	5 Po	CXL	10.0	
Cucumber	0.5	CXL		No U.S. registration.
Gherkin	0.5	CXL		No U.S. registration.
Melons, except watermelon	2	CXL		No U.S. registration.
Persimmon, Japanese	2 Po	CXL		No U.S. registration.
Pome fruits	5 Po	CXL		No U.S. registration.
Potato	5 Po <sup>b</sup>	CXL		No U.S. registration.
Raspberries, Red, Black	2	CXL		No U.S. registration.
Strawberry	2	CXL		No U.S. registration.
Wheat	0.01(*) <sup>c</sup>	CXL	0.1 for grain	
Wheat straw and fodder, Dry	0.1	CXL	0.5 for forage, hay, and straw	

<sup>a</sup> Po = Postharvest treatment of the commodity.

<sup>b</sup> Washed before analysis.

<sup>c</sup> Asterisk designates MRL set at the limit of quantitation.

## DIETARY EXPOSURE ASSESSMENT

The results from the revised acute and chronic analyses of imazalil were all below HED level of concern for all population subgroups. Cancer dietary exposure estimate exceeded HED's level of concern. Anticipated residues and dietary exposure/risk analyses for tolerance reassessment are found in "Anticipated Residues and Cancer, Acute and Chronic Dietary Exposure Analyses for Imazalil.", dated January 24, 2002, T. Morton, DP Barcode: D280449.

## AGENCY MEMORANDA RELEVANT TO REREGISTRATION

DP Barcode: None  
Subject: Imazalil. DEB Phase 4 Review.  
From: S. Funk  
To: K. Davis  
Dated: 10/18/90  
MRID: None

DP Barcode: D164394  
Subject: Protocol for Determination of the Nature of the Residue in Ruminants for Imazalil.  
From: S. Funk  
To: K. Davis  
Dated: 7/2/91  
MRID: None

DP Barcode: D165032  
Subject: Protocols for the Citrus Processing and Winter Wheat Field Trials for Imazalil.  
From: S. Funk  
To: K. Davis  
Date: 7/16/91  
MRID(s): None

DP Barcode: D168504  
Subject: Reregistration of Imazalil. Janssen Pharmaceutica 90 Day Response to Phase 4 DCI.  
From: S. Funk  
To: K. Davis  
Dated: 12/3/91  
MRID: None

DP Barcode: D168495  
Subject: Response to Registrant's Concerns/Questions Arising from the Imazalil Phase 4 Reregistration DCI.  
From: B. Cropp-Kohlligian  
To: B. Briscoe  
Dated: 1/28/92  
MRID: None

DP Barcode: D171401  
Subject: ID# 111901-43813. Imazalil. Response to Phase IV Review.  
From: L. Cheng  
To: K. Davis  
Dated: 2/4/92  
MRID: 42012005 through 42012009

DP Barcode: D173008  
Subject: Reregistration of Imazalil. Protocol for Nature of the Residue in Wheat.  
From: S. Funk  
To: K. Davis  
Date: 2/25/92  
MRID(S): None

DP Barcode: D179225  
Subject: Reregistration of Imazalil. Poultry Metabolism Protocol.

From: S. Funk  
 To: K. Davis  
 Dated: 8/6/92  
 MRID: None

DP Barcode: D170886  
 Subject: Imazalil Reregistration. Magnitude of the Residue - Post Harvest Treatment of Bananas (Foreign). Guideline 171-4k (Magnitude of the Residue - Crop Field Trial).  
 From: A. Aikens  
 To: B. Briscoe and K. Davis  
 Date: 8/13/92  
 MRID: 42058701

DP Barcode: D181319  
 Subject: Imazalil: FIFRA 6(a)(2) Data and Reregistration. Processing Studies for Citrus: Preliminary Findings.  
 From: S. Funk  
 To: K. Davis  
 Dated: 9/3/92  
 MRID: 42348301 and 42405501

DP Barcode: D179225  
 Subject: Reregistration of Imazalil. Poultry Metabolism Protocol. Addendum to Memorandum of 8/6/92.  
 From: S. Funk  
 To: K. Davis  
 Dated: 9/24/92  
 MRID: None

DP Barcode: D181284  
 Subject: Imazalil. Product Chemistry Data and Stability of <sup>3</sup>H-Imazalil.  
 From: L. Cheng  
 To: K. Davis  
 Dated: 9/25/92  
 MRID: 42403101 and 42403102

DP Barcode: None  
 Subject: Non-concurrence on Draft FR Notice. PP#5F3250. Imazalil on Forage and Hay of Wheat and Barley.  
 From: R. Cook  
 To: C. Giles-Parker  
 Date: 1/7/93  
 MRID(s): None

DP Barcodes: D182706 and D186541  
 Subject: Imazalil, Reregistration. Nature of the Residue in Ruminant and Analytical Methods for Plants.  
 From: J. Abbotts  
 To: K. Depukat  
 Dated: 2/17/93  
 MRID: 42454801 through 42454804, and 42593602

DP Barcode: D182575  
 Subject: Imazalil. Citrus processing Studies.  
 From: S. Funk

To: K. Davis  
Dated: 2/17/93  
MRID: 42454806

DP Barcode: D187775  
Subject: Imazalil: Citrus and Citrus Processed Commodities Storage Stability.  
From: S. Funk  
To: K. Depukat  
Date: 3/2/93  
MRID(s): 42643301

DP Barcode: D189000  
Subject: Imazalil: (1) Wheat Processing Waiver Request; (2) Poultry Metabolism Protocol Change.  
From: S. Funk  
To: K. Davis and K. Depukat  
Date: 4/6/93  
MRID(s): None

DP Barcode: None  
Subject: Meeting with Janssen Pharmaceutica, 4/28/93, on Imazalil Metabolism in Goat.  
From: J. Abbotts  
To: K. Depukat  
Dated: 4/30/93  
MRID: None

DP Barcode: D182707  
Subject: Imazalil (List B; Case 2325; Chemical 111901): Analytical Method for the Determination of Imazalil and R14821 in/on Bananas, Citrus, and Citrus Processed Commodities. Research Method and Enforcement Method Comparison.  
From: S. Funk  
To: K. Depukat and K. Davis  
Dated: 6/24/93  
MRID(s): 42454803 through 42454805

DP Barcode: D193375  
Subject: Imazalil, Reregistration. Nature of the Residue in Ruminant, Supplemental Data.  
From: J. Abbotts  
To: K. Depukat  
Dated: 8/17/93  
MRID: 42838201

DP Barcode: D194053  
Subject: FAP#3H5680. Reregistration of Imazalil. Petition for a Revised Tolerance for Banana Pulp (PP#8E2100). Petition for a Revised Food Additive Tolerance for Citrus Oil.  
From: S. Funk  
To: C. Giles-Parker, J. Stone, K. Davis, and K. Depukat  
Dated: 11/3/93  
MRID: None

DP Barcode: D195726  
Subject: Imazalil (List B, Chemical 111901, Case 2325). Nature of the Residue in Poultry (Preliminary).  
From: S. Funk  
To: K. Davis and K. Depukat



Date: 11/17/93  
MRID: 42949401

DP Barcode: D191318  
Subject: Imazalil. Storage stability in Wheat (Grain, Forage, and Straw).  
From: D. Miller  
To: K. Depukat  
Date: 11/18/93  
MRID: 42755301

DP Barcode: D194151  
Subject: Reregistration of Imazalil (List B, Chemical 111901, Case 2325). Magnitude of the Residue in Wheat and Barley (171-4(k)) and in Processed Commodities of Wheat and Barley (171-4(l)).  
From: S. Funk  
To: K. Davis and K. Depukat  
Dated: 12/21/93  
MRID: 42852001, 42852002, and 42868101

DP Barcode: D187506  
Subject: Imazalil. Case No. 2325. Registrant's Response to Reregistration.  
From: L. Cheng  
To: K. Depukat  
Dated: 1/10/94  
MRID: 42626901 through 42626903

DP Barcode: D198235  
Subject: Imazalil. Case 2325. Phase IV Review of Orange and Banana Metabolism Studies.  
From: L. Cheng  
To: K. Depukat  
Dated: 5/3/94  
MRIDs: 42012008 and 42012009

DP Barcode: D197176  
Subject: PP4F3096: Imazalil (Fungaflor 500 EC) in/on Pears. Amendment Dated 11/22/93.  
From: M.I. Rodriguez  
To: C. Giles-Parker, J. Stone, and A. Kocialski  
Dated: 6/2/94  
MRID: None

DP Barcode: D189963  
Subject: Imazalil. Case 2325. Registrant's Response to Magnitude of the Residue in/on Bananas.  
From: L. Cheng  
To: K. Depukat  
Dated: 7/14/94  
MRID: 42710501

DP Barcode: D198599  
Subject: Imazalil. Case No. 2325. Nature of the Residue in Laying Hen.  
From: L. Cheng  
To: K. Depukat  
Dated: 7/14/94

MRID: 43076101

DP Barcode: None  
 Subject: Imazalil. Hen and Ruminant Metabolism Studies. To be Presented to the HED Metabolism Committee on August 8, 1994.  
 From: L. Cheng  
 To: HED Metabolism Committee  
 Dated: 8/4/94  
 MRID: None

DP Barcode: None  
 Subject: Imazalil. Laying Hen and Lactating Goat Metabolism. The Metabolism Committee Meeting Held on August 18, 1994.  
 From: L. Cheng  
 To: The HED Metabolism Committee  
 Dated: 8/30/94  
 MRID(s): None

DP Barcode: D205954  
 Subject: Imazalil. Case No. 2325. Supplemental Data to Orange Metabolism Study.  
 From: L. Cheng  
 To: K. Depukat  
 Dated: 9/22/94  
 MRID: 43308401

DP Barcode: None  
 Subject: Imazalil. Case No. 2325. Residues to be Measured in the Animal Feeding Studies.  
 From: L. Cheng  
 To: K. Depukat  
 Dated: 11/1/94  
 MRID(s): None

DP Barcode: D206723  
 Subject: Imazalil. Case No. 2325. Rebuttal to Geographic Representation for Postharvest Use: Bananas.  
 From: L. Cheng  
 To: K. Depukat  
 Dated: 11/29/94  
 MRID: None

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 Subject: Imazalil. Case No. 2325. Metabolism on Banana - Postharvest Treatment. Review of Protocol.  
 From: L. Cheng  
 To: K. Depukat  
 Dated: 1/3/95  
 MRID: None

DP Barcode: D205092  
 Subject: Imazalil. Case No. 2325. Magnitude of Residue in Winter Wheat Forage, Straw and Grain Grown From Treated Seed.  
 From: L. Cheng  
 To: K. Depukat  
 Dated: 1/20/95  
 MRID: 43285001

DP Barcode: D215063  
 Subject: Imazalil - Application of DES Proviso to Existing Feed Additive Tolerances  
 From: G. Kramer  
 To: Chemistry Branch Files  
 Dated: 5/12/95  
 MRID: None

DP Barcode: D214575  
 Subject: Imazalil. Case No. 2325. Residue Analytical Method for the Animal Feeding Studies.  
 From: L. Cheng  
 To: K. Depukat  
 Dated: 6/8/95  
 MRID(s): None

DP Barcode: D220386  
 Subject: Imazalil (Chemical 111901, Case 2325, List B): Citrus Oil Food Additive Tolerance.  
 From: S. Funk  
 To: N. Nazmi and W. Hazel  
 Dated: 5/8/96  
 MRIDs: 92072030 and 92072040

DP Barcode: D224876  
 Subject: Imazalil. Case 2325. Metabolism on Bananas From Post-Harvest Treatment.  
 From: L. Cheng  
 To: P. Deschamp  
 Dated: 6/12/96  
 MRID(s): 43965701

DP Barcode: D239118  
 Subject: Imazalil (Chemical 111901, Case 2325, List B). GLN 860.1480. Protocol for a Ruminant Feeding Study.  
 From: S. Funk  
 To: D. Monos and W. Waldrop  
 Dated: 10/30/97  
 MRID: None

DP Barcode: D247703  
 Subject: Imazalil (111901), Registrant response to Poultry Feeding Study.  
 From: S. Piper  
 To: K. Farwell  
 Dated: 9/18/98  
 MRID: None

DP Barcode: D238452  
 Subject: Imazalil (Chemical 111901, Case 2325, List B). Analytical Method - Ruminants  
 From: S. Piper  
 To: M. Metzger  
 Dated: 1/20/99  
 MRID: 44337701

DP Barcode: D245510

Subject: Imazalil (Chemical 111901, Case 2325, List B). Janssen Pharmaceutica. GLN 860.1480. Ruminant Feeding Study.  
From: S. Piper  
To: M. Metzger  
Dated: 1/22/99  
MRID: 44568301

DP Barcode: D242498  
Subject: Method Validation for a Proposed Enforcement Method - Animal Commodities.  
From: David E. Hrady, Biologist  
To: Susan V. Hummel, Branch Senior Scientist  
Dated: 1/19/00  
MRID: 44455601

DP Barcode: D244510  
Subject: Radiovalidation of PAM Vol. II Method Using Samples From Banana Metabolism Study.  
From: David E. Hrady, Biologist  
To: Susan V. Hummel, Branch Senior Scientist  
Dated: 1/19/00  
MRID: 44532901

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